



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Clozapine	
Other means of identification		
Catalog number	1142107	
CAS number	5786-21-0	
Chemical name	8-Chloro-11-(4-methyl-1-piperazinyl)-5H-dibenzo[b,e][1,4]diazepine	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 3
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Toxic if swallowed. May cause drowsiness or dizziness.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.	
<b>Response</b>	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.	
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.	
<b>Supplemental information</b>	Pharmacologically active material.	

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Clozapine		5786-21-0	100

### 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a poison center or doctor/physician if you feel unwell.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested.
<b>Most important symptoms/effects, acute and delayed</b>	Pharmacologically active material. Occupational exposure may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically. Treatment of clozapine overdose may include the following: Establish and maintain a patent airway. Ensure adequate oxygenation and ventilation. Induced vomiting is not recommended, due to the potential for CNS depression and seizures. To decrease absorption, administer activated charcoal as a slurry within 6 hours of ingestion. Activated charcoal, which may be used with sorbital, may be more effective than gastric lavage. Consider gastric lavage if it can be performed within 1 hour of ingestion. Protect airway by placement in the Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first. Use physostigmine, dihydroergotamine, angiotensin, or norepinephrine to counteract anticholinergic symptoms. Treat hypotension with isotonic fluid infusion. If hypotension persists, administer dopamine or norepinephrine and titrate to desired response. Do NOT use quinidine or procainamide to treat cardiac arrhythmias. For seizures, administer diazepam or lorazepam. Consider phenobarbital or propofol if seizures recur after diazepam. Monitor for elevated liver enzymes, granulocytopenia, tachycardia, antimuscarinic effects, hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Monitor cardiac and vital signs, especially respiration, for several days because of possibly delayed effects. Provide assisted ventilation, if needed. Forced diuresis, dialysis, hemoperfusion, and exchange transfusion are not likely to be of benefit.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS.
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**Methods and materials for containment and cleaning up**

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

**Environmental precautions**

Avoid discharge into drains, water courses or onto the ground.

**7. Handling and storage****Precautions for safe handling**

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities**

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

**8. Exposure controls/personal protection****Occupational exposure limits****Exposure limit values****Industrial Use  
Material****Type****Value**

Clozapine (CAS 5786-21-0)

TWA

0.1 mg/m3

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection****Hand protection**

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Other**

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

**9. Physical and chemical properties****Appearance**

Appearance descriptions are general information and not specific to any USP lot.

**Physical state**

Solid.

**Form**

Powder.

**Color**

Yellow.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

359.6 - 366.8 °F (182 - 186 °C)

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Insoluble.
<b>Solubility (other)</b>	Acetone: Soluble. Alcohol: Soluble. Chloroform: Soluble.
<b>Partition coefficient (n-octanol/water)</b>	3.23
<b>Auto-ignition temperature</b>	> 680 °F (> 360 °C)
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Tricyclic dibenzodiazepine derivative.
<b>Dust explosion properties</b>	
<b>Minimum ignition energy (MIE) - dust cloud</b>	10 - 30 mJ
<b>Molecular formula</b>	C18H19ClN4
<b>Molecular weight</b>	326.82

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	May cause drowsiness and dizziness.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Toxic if swallowed. Based on information from therapeutic use, this material may cause: Agranulocytosis.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Seizures. Central nervous system effects. Cardiovascular effects. Fever. Blurred vision. Weight gain. Sweating. Gastrointestinal disturbances.

### Information on toxicological effects

<b>Acute toxicity</b>	Toxic if swallowed.
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Product	Species	Test Results
Clozapine (CAS 5786-21-0)		
Oral		
LD50	Rat	172 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Carcinogenicity	Based on available data, the classification criteria are not met.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Knowledge about health hazard is incomplete.	
Reproductivity		
40 mg/kg/day Reproductivity		
Result: No fetal harm was observed in animals.		
Specific target organ toxicity - single exposure	Narcotic effects.	
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.	
Aspiration hazard	Based on available data, the classification criteria are not met.	
Further information	Pharmacologically active material. Occupational exposure may cause physiological effects.	
12. Ecological information		
Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
Persistence and degradability	No data is available on the degradability of this substance.	
Bioaccumulative potential		
Octanol/water partition coefficient log Kow		
3.23		
Mobility in soil	No data available.	
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	
13. Disposal considerations		
Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.	
Local disposal regulations	Dispose in accordance with all applicable regulations.	
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.	
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).	
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.	
14. Transport information		
DOT		
UN number	UN2811	
UN proper shipping name	Toxic solid, organic, n.o.s. (Clozapine)	

**Transport hazard class(es)****Class** 6.1**Subsidiary risk** -**Packing group** III**IATA****UN number** UN2811**UN proper shipping name** Toxic solid, organic, n.o.s. (Clozapine)**Transport hazard class(es)****Class** 6.1**Subsidiary risk** -**Packing group** III**Other information****Passenger and cargo aircraft** Allowed with restrictions.**Cargo aircraft only** Allowed with restrictions.**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.**DOT; IATA****General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

**15. Regulatory information****US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes**Classified hazard categories**Combustible dust  
Acute toxicity (any route of exposure)  
Specific target organ toxicity (single or repeated exposure)**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations****California Proposition 65**

**WARNING:** This product can expose you to Clozapine, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California Proposition 65 - CRT: Listed date/Developmental toxin**

Clozapine (CAS 5786-21-0)

Listed: October 1, 1992

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

**Issue date** 06-17-2009

**Revision date** 05-29-2019

**Version #** 05

**Further information** Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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